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08/150-587 12/02/93 KEMPF

P 1634-HB-P11

EXAMINER

FAN, J

ART UNIT

PAPER NUMBER

12M2/1228

9

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1203

DATE MAILED:

12/28/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 10/26/94 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892. 2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474. 6.

Part II SUMMARY OF ACTION

1. Claims 1-10, 12-20, 29 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-7, 8, 12-20, 29 are rejected.

5. Claims 9, 10 are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other _____

EXAMINER'S ACTION

The specification is again objected to for reasons of record. Applicants' remarks have been carefully considered, but are deemed unpersuasive for the following reasons:

1. The specific, practical benefit of a pharmaceutical product in human and animal needs to be supported by factual evidence. A compound with promising in vitro properties may still fail to qualify as a useful drug for many reasons, such as absorption, transport, metabolism and elimination and can be accepted only after a thorough assessment of its pharmacologic, pathologic and clinical effects. Its effectiveness in vivo must be proved, first in experimental animals and finally in human.
2. The limited in-vitro data are not representative of all the compounds derived from all the variables and numerous permutations and combinations.

Claims 1-7, 12-20 are again rejected under 35 USC 112 first paragraph for reasons stated above.

Claims 1-7, 12-20 are again rejected under 35 USC 112 first and second paragraphs for reasons of record. Applicants' remarks have been carefully considered, but are deemed unpersuasive. It is noted that claims should be read in light of the specification, it is not permissible to read limitations from the specification into the claims. *In re Priest* 199 USPQ 11. It is not understood why the proviso statement is in the claims. Are there art compounds? or inactive compounds containing in the proviso statement.

OK to withdrawn
Claims 8, 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The two claims are duplicate of each other.

Claims 9-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The improper Markush rejection and 101 rejection over the two co-pending applications are hereby withdrawn in view of applicants' remarks.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

JTF DECEMBER 21, 1994

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

J.T. Fan
JANE T. FAN
PRIMARY EXAMINER
ART UNIT 123